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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,178	07/24/2003	Horst Surburg	3968.088	3190

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AKERMAN SENTERFITT
P.O. BOX 3188
WEST PALM BEACH, FL 33402-3188

EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/626,178	SURBURG ET AL.	
	Examiner	Art Unit	
	Rosalynd Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-25 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20-23 and 28-33 is/are rejected.
- 7) ☒ Claim(s) 19, 24 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/3/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 17-25 and 28-33 are pending.
Claims 17, 18, 20-23, 28-33 are rejected.
Claims 19, 24, and 25 are objected.
Claims 1-16, 26 and 27 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18, 2006 has been entered.

Priority

3. The first sentence(s) of the specification needs to be updated to reflect the current status of divisional Application No. 09/099,860 as abandoned.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

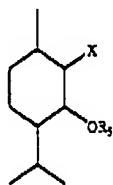
A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanke (US 6,231,900 B1).

Hanke teaches a confectionary product and preparation comprising physiological cooling



agents having the claimed formula, , wherein X is defined as being hydrogen or hydroxyl and R₅ is defined as being an *optionally* (emphasis added) hydroxyl substituted aliphatic radical containing up to 25 carbon atoms, preferably up to 5 carbon atoms (see column 4, lines 1-18). This corresponds to the instant compound having the claimed formula wherein R¹ is an alkyl group having 1 to 4 carbon atoms, R³ is a monocyclic saturated carbon system having 6 carbon atoms that is further substituted with alkyl groups having 1 to 4 carbon atoms and x is 0 (see entire disclosure, in particular column 1, lines 10-30; column 2, lines 4-6; column 2, line 26 to column 3, line 15; column 4, lines 1-24; column 7, lines 41-45 and examples 1 and 2). The confectionary product is disclosed as being in various forms including hard and soft candies, chewing gum and pastilles (see column 2, lines 32-35). Thus, the limitation that the preparation be ingested as a solid is taught. The cooling agent is present in an amount from about 0.01 to about 15% (see column 5, lines 41-45). The confectionary product is disclosed as comprising both a coolant composition and a flavor composition (see column 2, lines 26-35). The products are disclosed as having good throat soothing properties (see column 1, lines 5-9). The products

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disclosed by Hanke are administered in the same manner and amounts as the rhinologically active substances of the instant invention. Thus, Hanke inherently teaches the claimed method, especially since Hanke teaches that his confectionary product has a cooling effect and is suitable for the relief of cough and cold like symptoms. The claimed method is further inherently taught since when digested the confectionary product of Hanke would necessarily perform the claimed method.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 17, 18, 20-23, 28-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuribayashi et al. (US 5,756,857) in view of Wolff (Burger's Medicinal Chemistry and Drug Discovery, fifth edition, Volume 1: Principles and Practice, March 1995, pages 58, 59 and 785-788).

Kuribayashi et al. teach a cyclohexanol derivative which is useful for imparting a refreshing, cooling feeling to the mouth (see entire disclosure, in particular column 2, line 24 to column 4, line 22; column 14, lines 36-55; column 17, lines 1-20 and column 22, line 58 to column 23, line 13).

Kuribayashi et al. differ from the instant claims in that the rhinologically active of Kuribayashi et al. includes a OH substituent on their monocyclic saturated carbon system.

Wolff teaches that bioisosterism recognizes that substitution of an atom or group of atoms for another atom or group of atoms having similar size, shape and electron density generally provides compounds having similar biological activity (see page 59). Wolff teaches that OH and CH₃ are bioisosteres (see pages 785-786).

One having ordinary skill in the art at the time the invention was made would have found it obvious to replace the OH group in the compound of Kuribayashi et al. with a CH₃ group, as taught by Wolff, to impart a refreshing cooling feeling to the mouth, since Wolff teach that OH and CH₃ groups are

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bioisosteres and that the replacement of one for the other would result in a compound have similar biological properties.

Response to Amendment

Claim Rejections - 35 USC § 112

8. The rejection of claims 22 and 23 under 35 U.S.C. 112, first paragraph, is withdrawn.

Claim Rejections - 35 USC § 102

9. The rejection of claims 17-21, 26, and 27 under 35 U.S.C. 102(b) as being anticipated by Jarboe et al. (US 3,128,772) is withdrawn due to the amendment to claim 17, filed December 18, 2006 and the cancellation of claims 26 and 27.

10. The rejection of claims 17, 18, 20-22 and 28 under 35 U.S.C. 102(e) as being anticipated by Hanke (US 6,231,900 B1) is withdrawn due to the amendment to claims 17 and 28, filed December 18, 2006.

11. The rejection of Claims 17, 18, 21-23 and 28 under 35 U.S.C. 102(e) as being anticipated by Hughes (US 6,294,154 B1) is withdrawn due to the amendment to claims 17 and 28, filed December 18, 2006.

Claim Rejections - 35 USC § 103

12. The rejection of claims 17, 19, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Hanke (US 6,231,900 B1) is withdrawn due to the amendment to claims 17 and 19, filed December 18, 2006 and the cancellation of claims 26 and 27.

13. The rejection of claims 17, 19, 20, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes (US 6,294,154 B1) is withdrawn due to the amendment to claims 17 and 19, filed December 18, 2006 and the cancellation of claims 26 and 27.

Response to Arguments

14. Applicant's arguments filed December 18, 2006 have been fully considered but they are not persuasive.

The Applicants argue that Hughes and Hanke fail to disclose or suggest using the claimed rhinologically active substances with formula (I) for achieving a clearing feeling. This argument is not persuasive because the confectionary product disclosed by Hanke would necessarily achieve a clearing feeling when ingested and the applicants have simply discovered a new result and/or property which was already present in the confectionary product of Hanke. The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978).

The Applicants further argue that obviousness cannot be predicated on what is unknown," Application of Sporman, 363 F.2d 444, 448 (CCPA 1966) (emphasis added). Clearly, Hanke does not disclose or suggest using cooling agents as flavor agents as in the claimed invention. This argument is not persuasive because the rejection is based upon anticipation and not obviousness. As disclosed above anticipation can be found based upon an unknown result or property. The Examiner believes that claims 30-33 are unpatentable over Hanke for at least the reasons disclosed above.

15. Applicant's arguments, see pages 13-15 of Applicants' remarks, filed December 18, 2006, with respect to the rejection of claims 17, 18, 20-22, 25 and 28 under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (US 3,993,604) have been fully considered and are persuasive. The rejection of claims 17, 18, 20-22, 25 and 28 has been withdrawn.

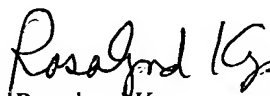
Allowable Subject Matter

16. Claims 19, 24 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M, W & F 5:30-7:30 am & 1-5 pm; T & Th 5:30 am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Rosalynd Keys
Primary Examiner
Art Unit 1621

January 5, 2007